



A new postural device for the treatment of positional obstructive sleep apnea. A pilot study



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ABSTRACT

Background: Approximately 60% of obstructive sleep apnea (OSA) diagnoses are position-dependent, and avoidance of the supine position could represent an effective treatment. Nevertheless, the majority of the available anti-supine treatments result in discomfort and low adherence. This study evaluated the effectiveness of a new vibrating supine avoidance device in reducing time spent in the supine position and the apnea-hypopnea index (AHI) without affecting sleep structure. Furthermore, the tolerability and satisfaction were also scored.

Methods: Observational prospective study of patients suffering from positional OSA. They were treated with a vibrating device and followed up at the first and fourth weeks after starting the treatment, and further polysomnographic studies were conducted while patients' wore the device. The comparison of the results was carried out through non-parametric tests. Significance level was 5%.

Results: Twelve patients had complete data. The device reduced time spent in the supine position (from $51.5 \pm 14.8\%$ to $25.2 \pm 21.0\%$, $p = 0.005$), median AHI (from 30.7 (23.2–38.2) at baseline to 21.5 (12.4–24.3) at the fourth week, $p = 0.002$). Also an improvement in the minimum SaO₂ (from 82.2 ± 7.5 to 87.2 ± 3.6 at the 4th week) was also observed. No variations in sleep quality or quantity were identified. All patients evaluated the device positively.

Conclusion: Our device was effective in reducing the time spent in the supine position and improving AHI, SaO₂ variables and sleep architecture. The device was well tolerated by the patients.

1. Introduction

Obstructive sleep apnea (OSA) is a very common disorder that

displays a 24–26% prevalence among adult men and increases with age [1–3]. OSA is a recognized risk factor for arterial hypertension, cardiovascular and cerebrovascular diseases, road accidents and poor quality of life

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Abbreviations

OSA	Obstructive sleep apnea
AHI	Apnea-hypopnea index
CPAP	Continuous positive airway pressure
PSG	Standard polysomnography

TST	Total sleep time
BMI	Body mass index
ESS	Epworth Sleepiness Scale
EOG	Electrooculogram
SaO ₂	Oxygen saturation

[2,4–6]. Furthermore, it has been associated with increased all-cause mortality [7]. The number of apnea and hypopnea events per hour (apnea-hypopnea index–AHI) is used to define OSA severity and may guide the choice in treatment among the different therapeutic options now available. In severe OSA (AHI > 30/h), the first-choice treatment is the application of continuous positive airway pressure (CPAP), which is a cost-effective treatment [8] that improves quality of life and reduces cardiovascular risk and road accidents [9–12]. Nevertheless, the efficacy of this treatment is limited by poor adherence due to side effects or patient refusal of treatment.

The supine sleep position may affect OSA severity by increasing upper airway collapsibility [13–15], and approximately 60% of patients suffer from positional OSA, with an AHI in the supine position double the value of the AHI in the non-supine position [16]. “Positional patients” are generally younger, have less severe symptoms and are less obese than non-positional patients [16]. These patients tend to have poor adherence to CPAP, between 29 and 83% of patients adhering to the treatment, and in the long term, only approximately 50% of these patients continue using the treatment [17]. Furthermore, these patients usually need more elevated pressures in the supine position that could increase the discomfort and side effects of CPAP treatment [16].

In positional patients, avoidance of the supine position (so-called “positional treatment”) could reduce the frequency and severity of obstructive events [18,19] and the cardiovascular complications of OSA [20]. Several techniques and devices have been tested, such as a vibrating chest vest, wearable alarm, tennis ball device and positional sleeper composed of firm foam [17,21]. However, most of these devices are uncomfortable or difficult to assemble [22], discouraging their use.

We have developed a new postural device for positional OSA patients and have conducted a pilot study to evaluate its efficacy in reducing the AHI.

2. Methods

2.1. Design

This was an observational, prospective intervention study that was carried out over the course of four weeks to assess the efficacy of sleep position therapy in treating patients with positional OSA. The study took place in the Sleep Units of the OSI Araba University Hospital. This study is the first part (pilot study) of a more extensive ongoing project. The study was approved by the local ethics committee and ClinicalTrials.gov (ID: NCT03336515).

2.2. Outcomes

The primary outcome was a reduction in AHI while using the device. The secondary outcomes were a reduction in the time spent in the supine position and the maintenance of good sleep quality and patient satisfaction.

2.3. Participants

We enrolled fourteen patients submitted to nocturnal standard polysomnography (PSG) who were eligible for the study. Of these patients, 12 signed the informed consent form, and two refused to participate due to work engagements and a lack of time to repeat PSG at 1

and 4 weeks.

All included patients fulfilled the following inclusion criteria: age > 18 years; diagnosis of positional OSA by PSG in our Sleep Unit; AHI > 10/h; supine AHI value double the non-supine AHI value; total sleep time (TST) ≥ 180 min; time spent in the supine position > 30% of TST, and no previous CPAP treatment. The exclusion criteria were movement disability or difficulties in changing sleep position; morbid obesity (body mass index BMI ≥ 40 kg/m²); severe cardiovascular or respiratory diseases; cognitive impairment; sleep disorders other than OSA; Epworth Sleepiness Scale (ESS) > 12; pregnancy; and treatment with antidepressants, psychotropic drugs or nervous system stimulants. Moreover, drug addicts, hard alcohol drinkers (> 80 gr/day), professional drivers, shift workers and dangerous machinery operators were also excluded.

2.4. Main baseline variables

Demographic and anthropometric variables (age, sex, BMI, neck circumference and blood pressure), past medical history, current pharmacological treatment and PSG data were recorded at baseline. Additionally, PSG and anthropometric data were collected at the 1st and 4th week follow-up visits. At each visit, an ESS and visual analogical scales about satisfaction and side effects of the treatment were administered.

2.5. Standard nocturnal polysomnography (PSG)

A complete overnight PSG was performed at baseline and at 1 and 4 weeks after starting the study. According to the American Academy of Sleep Medicine guidelines [23] and the Spanish Sleep Apnea Recommendations [2], we used six electroencephalographic electrodes, frontal (F3–F4), central (C3–C4) and occipital (O1–O2), referred to contralateral mastoids (A1–A2) and adopted the international 10–20 system. We included ground and reference electrodes (Cz). The electromyogram was obtained using two chin electrodes, and an electrooculogram (EOG) was registered employing two different electrodes placed above the left and right outer cantus. The different sleep stages N1, N2, N3 (NREM) and REM were scored; arousals, oxygen saturation (SaO₂), apneas and hypopneas were identified. Apnea was defined by a drop (> 90%) in the airflow detected by nasal cannula and/or thermistor for at least 10 s. Hypopnea was defined by a reduction in airflow (> 30% and < 90%) for at least 10 s, with a drop of at least 3% in the SaO₂ and/or arousal from sleep. PSG was considered valid if TST was at least 180 min. All the technicians scoring PSG were blinded to the results of the study.

2.6. Delivery of the positional device

After the PSG study, each patient was provided with a positional device for four weeks. The importance of good compliance with the device was stressed at each follow-up visit during the study period. One and four weeks after the beginning of the study, patients were submitted to a further PSG study while wearing the device.

2.7. Positional device

This new positional device, developed by our research group in

collaboration with the SIBEL SL company, received a national and international patent (PCT/ES2010707108 and P26018USPC). It is a vibrating device with a surface area of 4 cm² and 14 gr of weight incorporating an accelerometer/actimeter, a vibrator and other sensors (Fig. 1a and b).

The device was placed on the patient's forehead using clips to a sticker; it was placed on an area where patients sweat (Fig. 1c). The device starts vibrating with increasing intensity and has four different vibration intensities when the patient lies in the supine position for more than 30 s. The vibration stops when the patient changes from the supine to the non-supine position. Unlike other commercially available positional devices, our device is not placed on the patient's chest but on his/her forehead. Some studies have demonstrated that not only the position of the thorax but also the position of the head with respect to the thorax could improve airway collapsibility in the supine position [24]. Furthermore, although the device could also be mounted in the thorax, we placed it on the forehead to exploit bone conduction of vibration and increase effectiveness in changing body position.

2.8. Statistical analysis

Data were analyzed with the SPSS version 16.0 program (IBM, Chicago, IL). The results for continuous variables were expressed as the mean and standard deviation or median and interquartile range if they do not fit the normal distribution and those for categorical variables as the frequency and percentage. Significance level was 5% for hypothesis testing. The effectiveness of the treatment was evaluated according to the results of the principal variable (reduction in AHI), and the baseline AHI was compared at the first and fourth weeks after starting the treatment by nonparametric tests, Friedman's test and then Wilcoxon's test if the first one was significant. This same method was used to

evaluate the secondary endpoints. As this study was a pilot study, sample size was not defined.

3. Results

The main baseline PSG characteristics of the 12 patients with complete data are shown in Table 1. The mean age was 46.5 ± 9.5 years (75% men), and the mean BMI was 25.7 ± 3.3 kg/m². The mean systolic and diastolic blood pressure was 124.7 ± 9.4 mmHg and 78.0 ± 5.8 mmHg, respectively, and four patients were diagnosed with systemic hypertension. Four patients were smokers, and two were habitual alcohol consumers. The mean ESS value was 6.7 ± 3.7. No differences in clinical characteristics after 4 weeks of follow-up were registered. The percentage of TST spent in the supine position was significantly reduced from 51.5 ± 14.8% at baseline to 16.4 ± 16.0% at the first week (p = 0.002) to 25.2 ± 21.0% at the fourth week, (p = 0.005). (Fig. 2).

Accordingly, a significant reduction in the median AHI was registered during the study, from 30.7 (23.2–38.2)/h at baseline, to 21.0 (13.7–28.7)/h at the first week (p = 0.004) to 21.5 (12.4–24.3)/h four weeks (p = 0.002) after starting treatment (Fig. 3).

Additionally, AHI in the supine position was collected, from 42.1 (36.1–55.0)/h at baseline, to 4.5 (0.13–20.2)/h at the 1st week (p = 0.002) to 13.0 (0.25–17.2)/h at the 4th week (p = 0.003) (Fig. 4).

Overall, 9.2 points of absolute reduction in the median AHI value (baseline vs 4 weeks) was registered (Fig. 3), reaching a 29.1 point reduction in the AHI in supine position (Fig. 4), and a relative reduction of 69.1%. A global reduction of the AHI was observed in all patients, with a global reduction of 30% at the fourth week. Similarly, an improvement in the minimum SaO₂ (from 82.7 ± 7.5 to 88.1 ± 3.7 and 87.2 ± 3.6) and in the percentage of time spent with SaO₂ < 90%

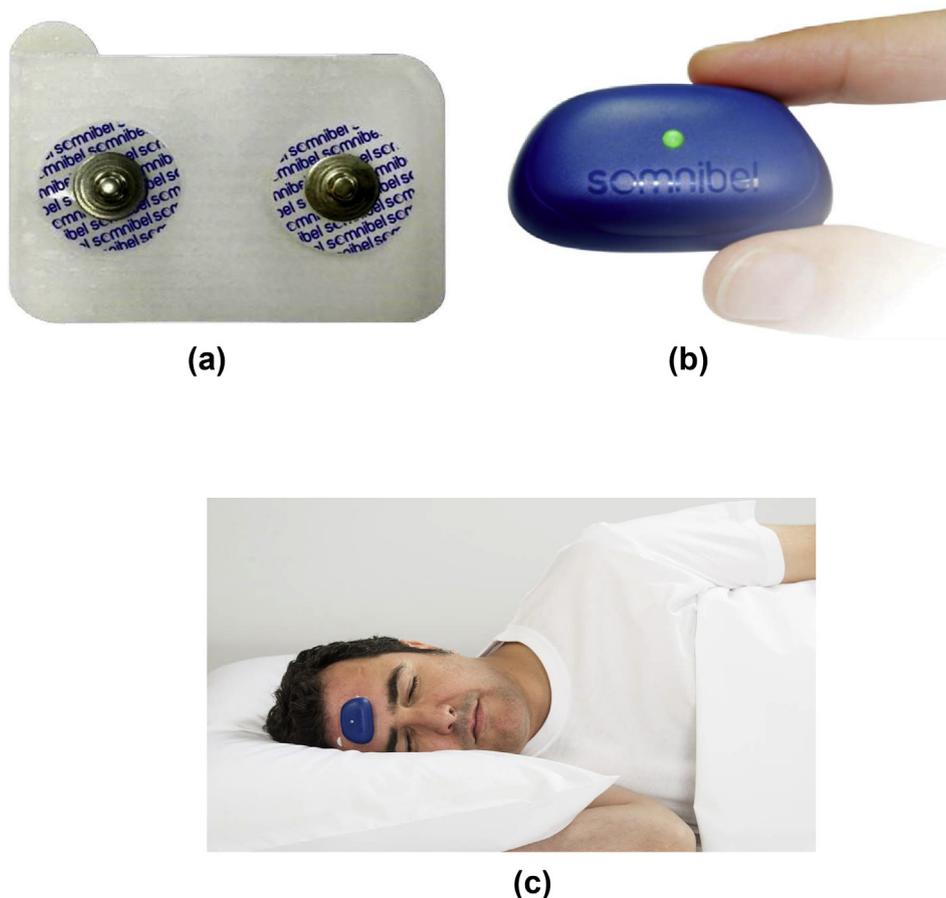


Fig. 1. a, b: Sticker of transdermal technology and our vibrational device. c: The device placed on the patient's forehead (reproduced with permission).

Table 1
Characteristics of PSG and results of treatment.

Characteristics (n = 12)	Baseline	1 week	4 weeks	P value
Total bed time (TBT)*	438.5 ± 41.1	435.0 ± 33.0	408.5 ± 43.6	0.046
Total sleep time (TST)	362.5 ± 36.6	347.7 ± 41.6	350.0 ± 45.6	0.779
% TST in the supine position**	51.5 ± 14.8	16.4 ± 16.0	25.2 ± 21.0	< 0.001
Sleep efficacy (TST/Registration time - %)	84.3 (75.5–90.9)	82.1 (76.9–84.9)	87.3 (72.2–89.0)	0.558
Sleep N1 minutes	19.5 ± 9.7	18.3 ± 9.1	15.6 ± 8.0	0.558
Sleep N2 minutes	47.9 ± 7.4	50.7 ± 6.6	51.3 ± 7.1	0.205
Sleep N3 minutes	18.9 ± 7.9	17.9 ± 5.9	19.6 ± 8.0	0.401
Sleep REM minutes	13.8 ± 4.3	13.9 ± 3.8	12.9 ± 5.1	0.758
% of Sleep N3 + REM	32.7 ± 8.6	31.8 ± 8.5	32.5 ± 7.8	0.436
Arousal index/hour***	33.0 ± 13.0	25.6 ± 10.2	23.4 ± 8.6	0.035
Apnea-hypopnea index/hour (AHI)****	30.7 (23.2–38.2)	21.0 (13.7–28.7)	21.5 (12.4–24.3)	0.001
AHI global reduction (%)	–	31.6	30.0	
AHI global reduction > 50% (%)	–	16.7	25.0	
AHI global reduction > 25% (%)	–	75.0	66.7	
AHI in the supine position*****	42.1 (36.1–55.0)	4.5 (0.13–20.2)	13.0 (0.25–17.2)	0.001
AHI reduction in the supine position (%)	–	89.3	69.1	
AHI in a non-supine position	14.0 ± 6.7	18.8 ± 8.3	17.7 ± 9.6	0.338
Minimum SaO ₂ (%)	82.2 ± 7.5	88.1 ± 3.7	87.2 ± 3.6	0.080
CT90 (% TST with SaO ₂ < 90%)	7.6 (0–23.7)	0.50 (0–1.8)	0.95 (0.03–7.8)	0.125
Compliance with the device (% days)	–	90.5%	92.3%	
Compliance with the device (hours/day)	–	6.5	6.7	

*p = 0.05 between week 1st and week 4th.

**p = 0.002 between basal and week 1st; p = 0.005 between basal and week 4th.

***p = 0.018 between basal and week 1st; p = 0.050 between basal and week 4th.

****p = 0.004 between basal and week 1st; p = 0.002 between basal and week 4th.

*****p = 0.002 between basal and week 1st; p = 0.003 between basal and week 4th.

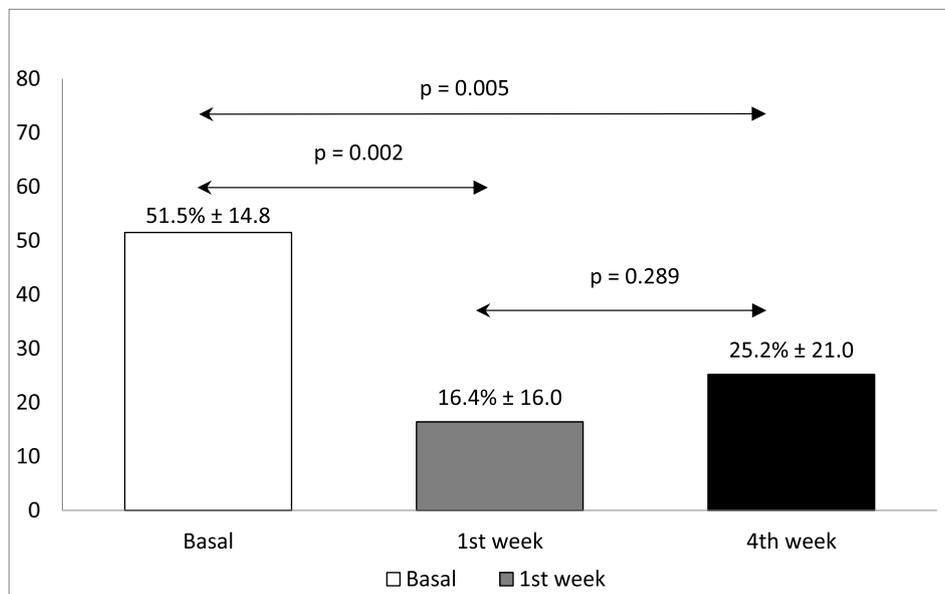


Fig. 2. % of the total sleep time (TST) in the supine position at baseline, 1st week and 4th week after using the device.

(from 7.6 (0–23.7) to 0.50 (0–1.8) and 0.95 (0.03–7.8)) were achieved after one and four weeks of treatment, respectively (Table 1).

No variations in sleep quality or quantity or increased sleep fragmentation were observed while using the device; conversely, a reduction in the arousal index was registered (Table 1). A visual-analogue scale (Appendix A) ranging from 0 to 10 (0 = the worst evaluation, 10 = the best evaluation) was used to score the tolerability of the positional device and patient satisfaction (Fig. 5). The results were quite homogeneous, with little variability across patients, and all the items received scores greater than 7.3 ± 1.8 , with 10 being the best score.

4. Discussion

In this pilot study, we show that the use of a vibrating device could

diminish the median AHI of patients with a positional OSA by up to 31.6% and 30% at the first and fourth weeks after starting treatment, respectively. Additionally, an improvement in the SaO₂ variables could also be obtained with the treatment. The achieved reduction in the time spent in the supine position could explain these results, and the use of our vibrating device does not affect sleep fragmentation.

Our results are in concordance with those of previous studies testing the efficacy of vibrating devices. In a crossover clinical trial, Bignold et al. [25] evaluated the effectiveness of a new vibrating device among 15 patients with positional OSA. The device was positioned on the patients' sternum and started vibrating when patients lied in the supine position for more than 30 s. The device was able to reduce both the total AHI by 45% with active treatment (p = 0.03) and the time spent in the supine position (from $19.3 \pm 4.3\%$ to $0.4 \pm 0.3\%$, p < 0.001).

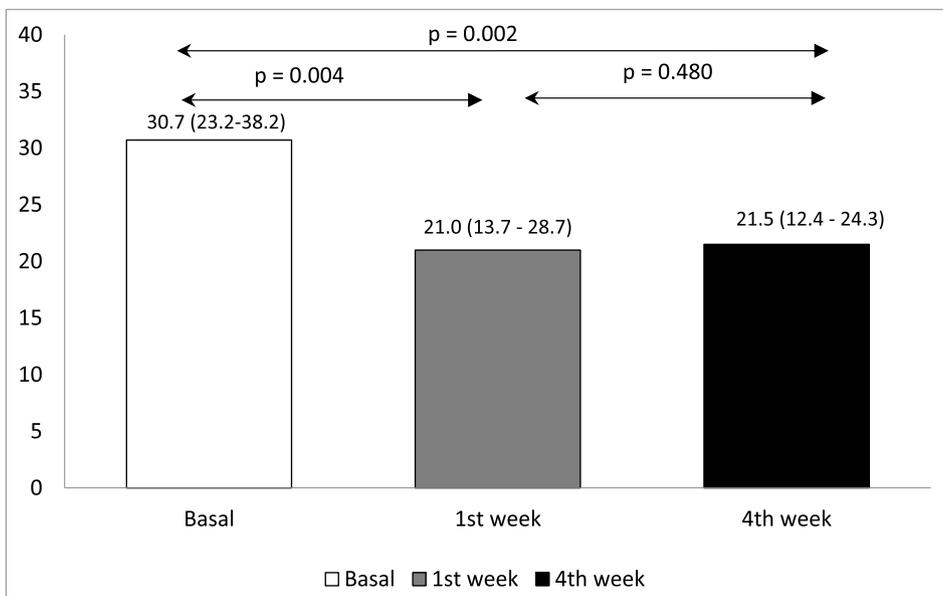


Fig. 3. Reduction in the median AHI value at each week.

Furthermore, the minimum overnight SaO₂ increased from 84.3 ± 1.3% to 88.3 ± 0.9%, p = 0.02. Similarly, Van Maanen et al. treated 30 patients with moderate positional OSA with a vibrating device placed at the back of the patients’ neck, and the vibration started when patients lied in the supine position for more than 10 s [26]. The mean AHI dropped from 27.7 ± 2.4/h to 12.8 ± 2.2/h. while using the device. Furthermore, the percentage of TST spent in the supine position decreased significantly from 40.0% in patients without the device to 19.0% (p = 0.00) in patients using the device. Dieltjens et al. also assessed the additional effect of a vibrating device under mandibular advancement device therapy in 20 patients with OSA [27]. The vibrating device without mandibular advancement reduced the overall AHI (from 20.8 events/h to 12.8 events/h) and also increased the minimum overnight SaO₂ from 84.7% to 88.0%, (p < 0.008). Finally, Eijsvogel et al. selected 27 patients who were treated with a vibrating device attached around their chest [28] and found a significant reduction between AHI at baseline (11.4 ± 4.9 events/h) and at the first week (3.9 events/h) with the vibrating device. These results showed more than a 20% reduction in TST. Moreover, a global AHI reduction of between 38% [27] and 65% [28] occurred. However, despite these encouraging results and the high prevalence of positional OSA, the

efforts of the scientific community to investigate and develop new devices to reduce the time spent in the supine position have been quite limited.

Over time, these vibrational devices could generate a conditioned reflex that avoids the supine position before the vibration starts. The main difference of this study was that our device was located on the forehead rather than the chest [25,27,28] or back of the neck [26]. We chose this placement because it results in better bone conduction through skull bones, which is similar to a resonance box [29]. Furthermore, this new approach might condition users to move from the supine position earlier. In addition, we hypothesized that the forehead position was important in OSA patients because it tends to maintain the head in a non-supine position, independent of body position, which could be enough to reduce the AHI index in moderate OSA.

In spite of its hopeful results, this pilot study has several limitations that should be taken into account; the reduced sample size and the limited follow-up period make it difficult to draw conclusions about patients’ long-term compliance with the device. Furthermore, the lack of a placebo group prevents the examination of the potential impact of a training/behavioral effect. Another randomized controlled clinical trial is ongoing to evaluate the effectiveness of this device vs placebo and

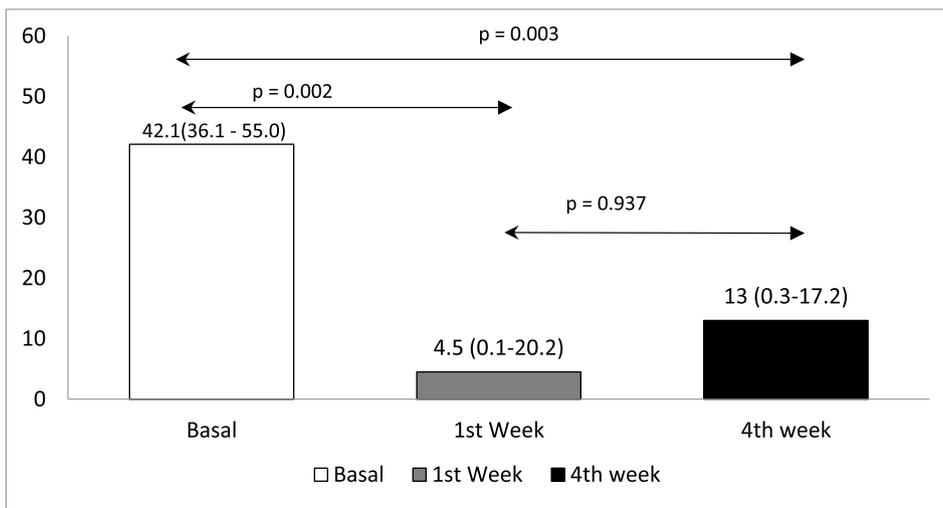


Fig. 4. Differences in the median AHI in the supine position between baseline 1st and 4th week.

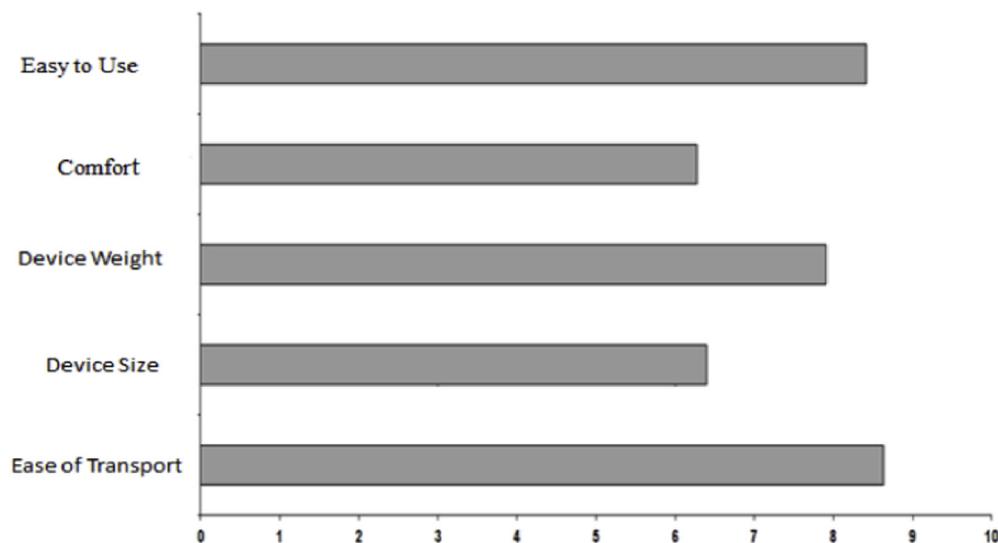


Fig. 5. Patients' tolerability of the positional device and satisfaction with treatment.

patients' long-term compliance with the device.

To our knowledge, this is the first device designed to be positioned on the patient's forehead. In addition, this innovative body position could increase comfort, leaving patients' thorax, back and neck free from unpleasant devices that limit their movements. Additionally, the device's absence of cables or belts, very light weight (14 gr) and small size make it comfortable, easy to use, and easy to transport. Also, the ease of assembly and wear and the automatic activation of the device could improve patients' motivation to use it. All of these characteristics could contribute to ensuring effectiveness without discouraging device use, as already suggested by the patients' good tolerability of the device.

In conclusion, this study suggests that this new elaborated device shows the effectiveness of positional therapy in reducing OSA and the supine position without disturbing patients' quality of sleep. Moreover, the device has good compliance and is comfortable for use among patients with positional OSA. This type of device could be very useful for patients with positional OSA. Further studies should confirm that the device on the forehead is as effective as a device on the chest or neck.

Conflicts of interest

The SibelMed Company provided the devices to carry out the study but did not take part in the study design, management of results or writing of the paper.

There was no economic contribution to the study by SibelMed.

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Authors' contributions

Joaquín Durán-Cantolla designed the study, reviewed the manuscript and contributed to all phases of the study.

Laura Hidalgo Armas & Cecilia Turino wrote the manuscript, collaborated in the recruitment of the patients and participated in the review of the manuscript.

Jose Cordero contributed to the statistical analysis of treatment data. Sandra Ingles contributed to the management of the patients and devices.

Jorge Ullate and Joaquin Durán-Carro collaborated in extracting data from the devices.

All authors commented on and edited the review drafts. All authors read and approved the final manuscript.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.rmed.2019.02.005>.

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